

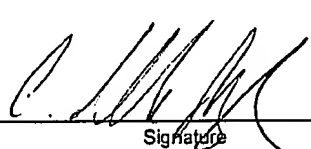
Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		Application Number	Filed
		09/933,709	August 22, 2001
		First Named Inventor	
		Charles A. Morris	
		Art Unit	Examiner
		1615	Kinshore, G.
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>Notice of Appeal previously filed on November 20, 2007.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number 53,835</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>		<p> Signature</p> <p>C. Allen Black, Jr. Typed or printed name</p> <p>412-355-6319 Telephone number</p> <p>January 22, 2008 Date</p>	
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			

<input checked="" type="checkbox"/> *Total of 1 forms are submitted.
--

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: 1615	:	
	:	
In re application of Morris, <i>et al.</i>	:	
	:	VITAMIN POWDER COMPOSITIONS
Serial No.: 09/933,709	:	
	:	
Filed: August 22, 2001	:	
	:	
Examiner: Gollamudi S. Kishore	:	
	:	
Mailstop AF: Commissioner for Patents		
P.O. Box 1450 , Alexandria, VA 22313-1450		

ARGUMENTS AND REMARKS FOR PRE-APPEAL BRIEF CONFERENCE

Sir:

In response to the Advisory Action of October 3, 2007 in the above identified application, Applicants request a Pre-Appeal Brief Conference in accordance with the guidelines in the "New Pre-Appeal Brief Conference Pilot Program" announcement, which appeared in the July 12, 2005 issue of the *Official Gazette*. In accordance with those guidelines, comments for the conference are presented herein. Filed concurrently herewith is a Pre-Appeal Brief Request for Review (form PTO/SB/33). The issues addressed herein are ripe for appeal in accordance with 37 C.F.R. § 41.31(a)(1), as the claims have been subject to at least two rejections.

Arguments

Applicants filed a Response to the Final Office Action, including proposed amendments, on September 21, 2007, which resulted in the Advisory Action mailed October 3, 2007. In the Advisory Action, the Examiner stated that the proposed amendment to claim 18 required further consideration and possibly another search. The substantive arguments presented in the Office Action reply mailed on September 21, 2007 were not addressed by the Examiner.

As a preliminary matter, Applicants request entry of the proposed amended claims as presented in the Response to Final Office Action mailed September 21, 2007 in order to make the claims ready for appeal. A review of the requested amendments shows that they present no new issues, but rather further clarify the claims to comply with the Examiner's suggestions in the June 21, 2007 Office Action. Further, the additional recitation of the vitamin being in "liquid phase" presents no new issues, because the element "liquid" was already present in searched claims 24, 28, 33, 37, and 41. In the non-final Office Action

mailed 6/21/07 (page 5), the Examiner stated that "Among the vitamins, B vitamins, vitamin A, [and] beta carotene are solids and not oils. Applicant has not shown that the silica particles having solids behave in the same way as oily vitamins." Although Applicants disagree with the Examiner's assertion, Applicants amended the claims in accordance with the Examiner's statement in the reply mailed September 21st. Therefore, it is respectfully requested that the previously presented amendments be entered as they present no new issues and removes issues from appeal.

Applicant's Invention

Broadly, Applicants' invention is directed to a free flowing composition comprising silica and a fat soluble vitamin. For example, in pending claim 18, the free-flowing composition comprises "about 5 to about 34 weight percent redried cornstarch; silica having a particle size of between 40 and 50 microns; and 65 to 80 weight percent of at least one fat soluble vitamin in liquid phase." Applicants demonstrated that the claimed combination is capable of being loaded with more vitamin than has been shown in the cited prior art.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner did not enter the minor amendments presented in the response to the Final Office Action (Response to Final Office Action dated September 21, 2007). Applicants note that these amendments do not present new issues as they are directed to clarifying the range of the claimed vitamin concentration (i.e., removing the term "at least" from claim 22 as noted by the Examiner), and further correcting the language of dependent claims to refer to only fat soluble vitamins in liquid phase in claim 23. Thus, Applicants respectfully request that the previously presented amendments be entered as they present no new issues and remove issues for appeal.

Rejections under 35 U.S.C. §103

Claims 18-44 and 47-52 were rejected under 35 U.S.C. § 103(a) as assertedly being obvious over the combination of U.S. Patent No. 4,486,435 to Schmidt (hereinafter the "Schmidt '435 patent"), in view of U.S. Patent No. 4,603,143 to Schmidt (hereinafter the "Schmidt '143 patent") and U.S. Patent 4,719,228 to Rawlins (hereinafter 'Rawlins' patent) or 'Rawlins' in view of Schmidt '435 or Schmidt '143. However, for at least the following reasons the Examiner has failed to formulate a *prima facie* case of obviousness since the combined references fail to teach or suggest, either expressly or inherently, each and every element of the claims.

Specifically, the Examiner has failed to identify any reference which teaches the claimed range of “silica having a particle size of between 40-50 microns.” (See, independent claims 18, 22, 26, and 29 as well as the dependent claims thereof). The Examiner characterized Schmidt ‘143, as “disclosing a free flowing, high density, fat-soluble vitamin powder preparation teaches the use of silica of bigger particle sizes (100 microns).” (Final Office Action mailed June 21, 2007, page 3.) The Examiner further stated that “it would have been obvious to use ... sizes 40-50 microns in the compositions of Schmidt, et al. ‘435 or ‘143 with a reasonable expectation of success, since as evidenced by Rawlins, one can obtain free-flowing powders which have a diameter of between 10 microns to 1 millimeter.” (*Id.* at page 4.) However, the Examiner fails to account for the fact that Schmidt ‘143 teaches away from using particle sizes of 40-50 microns. Schmidt ‘143 states that “the use of the described [a minimum length, width, or both of 300 microns] is **essential** to obtaining a free-flowing, fat soluble vitamin.” (U.S. Patent No. 4,603,143, col. 1, lines 46-50, emphasis added). Therefore, Schmidt ‘143 cannot be combined with the smaller particles of Schmidt ‘435 which teaches use of silica to encapsulate liquids with “a primary [silica] particle size of about 0.01 microns to about 0.04 microns.” (U.S. Patent No. 4,486,435, col. 3, lines 34-36). In fact, Schmidt ‘435 teaches the use of silica particles which are 1,000 times smaller than 40-50 micron range of claims 11, 22, 26, and 29, and thus, the reference is irrelevant. Consequently, Schmidt ‘143 and Schmidt ‘435 cannot be used, alone or in combination, to render the Applicants’ claims obvious because there is no rationale to combine or modify them to yield the claimed range.

The Examiner has also failed to identify any reference teaching the claimed loading density of “65 to 80 percent of at least one fat soluble vitamin.” (See independent claims 18, 22, 26, and 29 as well as the dependent claims thereof). The Examiner asserts that 60% loading is disclosed in Rawlins and that this is close enough to make an obviousness rejection. However, Rawlins does not disclose loading densities in a range of **65-80%**. Thus, the Examiner has failed to identify any reference teaching such high loading densities either alone or in combination. In fact, based on the cited references, one of ordinary skill in the art would not expect that such loading densities are even achievable, because such loading densities were not achieved.

In addition, the Examiner states that Rawlins teaches that Sipernat 50 is free-flowing. This is an incorrect reading of the reference which contradicts the conclusions of the Schmidt ‘143 reference, which states that “[a minimum length, width, or both of 300 microns] is **essential** to obtaining a free-flowing, fat soluble vitamin.” (Schmidt ‘143, *supra*). Rawlins teaches that silica ranging from 10 μ m to 1 mm (including Sipernat 50) in combination with a pharmaceutically active ingredient (i.e., indomethacin,

ketazolam, diazepam, digoxin, and 6-cyano-3,4-dihydro-2,2-dimethyl-trans-4-(2-oxo-1-pyrrolidiny)-2H-benzo[b]pyran-3-ol) is free-flowing. Rawlins **does not** disclose that a fat soluble vitamin can be made free-flowing, with silica having a particle size of between 40-50 microns as shown in the Declaration of Morris, attached. (Sept. 4, 2003, hereinafter the "Declaration '03"). In fact, contrary to the Examiner's assertion of Sipernat being generally free flowing between 10 μ m to 1 mm, the Declaration of Morris establishes that only a relatively narrow range is actually suitable for maintaining free-flowability of when loaded with a fat soluble vitamin. Thus, without any direction or guidance to the claimed range of fat soluble vitamins, Rawlins cannot render obvious (either alone or in combination) a silica particle in the 40-50 micron range which maintains free-flowability when fat soluble vitamin is absorbed at the levels recited in claims 18, 22, 26, and 29 as well as the claims dependent thereon. Thus, while the Office Action has identified some of the individual elements of the claims, a *prima facie* case of obviousness has not been established since the Examiner has not indicated where the cited references teach each and every element of the pending claims. Further, the evidence of record (i.e., the Declaration of Morris) establishes a secondary factor of non-obviousness. Hence, Applicants request withdrawal of the rejection.

To the extent, that the Examiner has repeatedly rejected the claims by asserting that the claimed composition would be obvious despite not being disclosed in the prior art, Applicants submitted further evidence to over come these rejections. See, Declaration, '03, attached. The Examiner erred in failing to consider the data presented in the Declaration '03 for its probative value as required by M.P.E.P. § 716.01(c). Specifically, the Declaration '03 objectively demonstrates that the claimed particle size ranges provided unexpectedly high loading densities of vitamin and that the size ranges of the silica were critical for achieving these densities. As stated in the M.P.E.P. § II(a) "[a]pplicants can rebut a *prima facie* case ... by showing the criticality of the claimed range. In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). The Declaration '03, shows that only the 40-50 micron range (not smaller or larger sizes of silica) results in a free-flowing powder and that these results are unexpected. Given that such a critical silica size range exists and has been conclusively demonstrated, Applicants respectfully submit that the 35 U.S.C. § 103(a) rejection is erroneous.

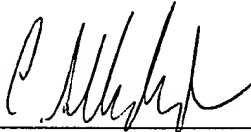
To the extent that the Examiner rejected the Declaration '03 as being "unscientific," such a rejection is arbitrary and capricious because the results presented in the '03 Declaration were performed by highly skilled artisans and signed with an oath. Specifically, the data was semi-quantitative which is

scientific according to previous court decisions. See attached, *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986) cited in M.P.E.P §716.01(a). The Examiner failed to explain why semi-quantitative data is somehow “unscientific;” therefore, absent any evidence to the contrary, the '03 Declaration establishes non-obviousness and the Examiner's characterization of the '03 Declaration as “unscientific” has no rational basis and the rejections should be withdrawn.

Claims 18-44 and 47-52 were further rejected under 35 U.S.C. § 103(a) as being obvious over the previously recited combinations of references further in view of U.S. Patent No. 4,010,073 to Drake; hereinafter “Drake.” Applicants maintain that the rejection is in error because, Drake teaches the use of starch to stabilize globular, water soluble protein compositions. Applicants note that the formulation chemistry in Drake is different than the pending claims because the active agent of Drake is a large, hydrophilic molecule; whereas, Applicants claim a small, hydrophobic molecule. Applicants reaffirm that one of ordinary skill in the art would not look to the storage stability of a globular protein for the formulation chemistry of a fat soluble vitamin, especially where the admixture could affect flowability. Drake does not teach how to use corn starch to improve stability of fat soluble molecules or how such stability can be improved while maintaining the free flowability of fat soluble molecules. However, the Examiner maintained that “the storage stability would remain the same irrespective [of] what the active agent is.” Office Action mailed 6/21/07, page 7. Applicants strongly disagree. There is no basis or support for this broad generalization by the Examiner. The Examiner has failed to identify any reference or rationale, which teaches that drug formulations using starch all have the same storage stability. As such, Drake cannot render the claims obvious.

For at least the foregoing reasons, Applicants submit that claims 18-24, 26-44, and 47-51 are in condition for allowance, which action is respectfully requested.

1/22/08
Date


C. Allen Black
Reg. No. 53,835